



Theratechnologies Receives FDA Approval for EGRIFTA WR™ (Tesamorelin F8) to Treat Excess Visceral Abdominal Fat in Adults with HIV and Lipodystrophy

Mar 25, 2025

New, improved formulation set to replace EGRIFTA SV®

MONTREAL, March 25, 2025 (GLOBE NEWSWIRE) -- Theratechnologies Inc. ("Theratechnologies" or the "Company") (TSX: TH) (NASDAQ: THTX), a commercial-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's supplemental Biologics License Application (sBLA) for the F8 formulation of tesamorelin for injection. The Company will commercialize the new formulation under the tradename *EGRIFTA WR™*.

Tesamorelin for injection is the only medication approved in the U.S. for the reduction of excess abdominal fat in adults with HIV who have lipodystrophy. The new formulation, *EGRIFTA WR™*, is a daily injectable but only needs weekly reconstitution. It requires less than half the administration volume as the current F4 formulation, sold in the U.S. as *EGRIFTA SV®*, which is reconstituted daily. Pharmacokinetic studies have shown bioequivalence of *EGRIFTA WR™* to the original F1 formulation of tesamorelin for injection (previously sold under the trade name *EGRIFTA®*). The most commonly reported adverse reactions of *EGRIFTA WR™* include arthralgia, injection site reactions, pain in extremity, peripheral edema, and myalgia.

"We are pleased to offer this improved, more convenient version of tesamorelin for injection to help people with HIV and their healthcare providers more effectively manage comorbidities like lipodystrophy, which today often presents as central adiposity," said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. "*EGRIFTA WR™* enables a simplified administration and an improved patient experience, which are important considerations for people living with HIV."

EGRIFTA WR™ will be supplied as four single-patient-use vials, each containing 11.6 mg of tesamorelin, sufficient for seven doses. The daily dose is 1.28 mg (0.16 mL of the reconstituted solution) injected subcutaneously. The product can be stored at room temperature (20° to 25° C [68° to 77° F]) before and after reconstitution.

"Central adiposity, characterized by the accumulation of excess visceral abdominal fat (EVAF), is a common complication for people with HIV that may result from the virus itself, from certain older antiretrovirals and from a reduction in growth hormone concentrations," commented David Alain Wohl, MD, Professor at the Institute of Global Health and Infectious Diseases, The University of North Carolina at Chapel Hill. "Given the significant impact of EVAF on health and quality of life for many of our patients with HIV, and the importance of maintaining lean muscle mass especially as we age, a new, more conveniently dosed formulation of tesamorelin is a welcome advancement."

EGRIFTA WR™ will be manufactured at a new, U.S.-based contract drug manufacturing organization (CDMO). The new formulation, which is patent protected in the U.S. until 2033, is set to replace *EGRIFTA SV®*.

Further information about *EGRIFTA WR™*, including full prescribing information, instructions for use, and important safety information is available [here](#).

Important Safety Information

EGRIFTA WR™ (tesamorelin for injection) is approved in the U.S. for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy*. *EGRIFTA WR™* is a growth hormone-releasing factor (GHRF) analog that acts on pituitary cells in the brain to stimulate the production and release of endogenous growth hormone.

Limitations of Use:

- Long-term cardiovascular safety of *EGRIFTA WR™* has not been established. Consider risk/benefit of continuation of treatment in patients who have not had a reduction in visceral adipose tissue.
- *EGRIFTA WR™* is not indicated for weight loss management as it has a weight-neutral effect.
- There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking *EGRIFTA WR™*.

Contraindications:

Do not use *EGRIFTA WR™* if a patient:

- Has disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma.
- Has active cancer.
- Is allergic to tesamorelin or any of the ingredients in *EGRIFTA WR™*.
- Is pregnant or planning to become pregnant.

The most commonly reported adverse reactions of *EGRIFTA WR™* include: arthralgia, injection site reactions, pain in extremity, peripheral edema, and myalgia.

Healthcare providers and patients are encouraged to report adverse events at 1-833-23THERA (1-833-238-4372). You are encouraged to report side effects of prescription drugs to the FDA. Visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088.

Refer to [this link](#) for the full prescribing information, patient information and instructions for use for *EGRIFTA WR™*.

About Theratechnologies

Theratechnologies (TSX: TH) (NASDAQ: THTX) is a specialty biopharmaceutical company focused on the commercialization of innovative therapies that have the potential to redefine standards of care. Further information about Theratechnologies is available on the Company's website at www.theratech.com, on SEDAR+ at www.sedarplus.ca and on EDGAR at www.sec.gov. Follow Theratechnologies on [LinkedIn](#) and [X](#).

Forward-Looking Information

This press release contains forward-looking statements and forward-looking information (collectively, the "Forward-Looking Statements") within the meaning of applicable securities laws, that are based on management's beliefs and assumptions and on information currently available to it. You can identify forward-looking statements by terms such as "may", "will", "should", "could", "promising", "would", "outlook", "believe", "plan", "envisage", "anticipate", "expect" and "estimate", or the negatives of these terms, or variations of them. The Forward-Looking Statements contained in this press release include, but are not limited to, statements regarding: (i) the convenience of the F8 formulation; (ii) the experience of using the F8 formulation for patients; and (iii) the transition to the F8 formulation from *EGRIFTA SV®*. Although the Forward-Looking Statements contained in this press release are based upon what the Company believes are reasonable assumptions in light of the information currently available, investors are cautioned against placing undue reliance on these statements since actual results may vary from the Forward-Looking Statements contained in this press release. Certain assumptions made in preparing the Forward-Looking Statements include that: (i) the marketplace will accept this new formulation of *EGRIFTA SV®*; and (ii) the F8 formulation of tesamorelin for injection will be reimbursed by private and public payors. Forward-Looking Statements assumptions are subject to a number of risks and uncertainties, many of which are beyond the Company's control, that could cause actual results to differ materially from those that are disclosed in or implied by such Forward-Looking Statements. These risks and uncertainties include, but are not limited to: (i) patients and physicians do not adopt the F8 formulation of tesamorelin for injection; (ii) the F8 formulation of tesamorelin for injection does not get reimbursement coverage from private and/or public payors; and (iii) the transition to the F8 formulation is delayed due to various matters, including delays associated with the availability of materials required to commercialize the F8 formulation. The Company refers current and potential investors to the "Risk Factors" section of the Company's annual information form filed under Form 20-F dated February 26, 2025 available on SEDAR+ at www.sedarplus.ca and on EDGAR at www.sec.gov under Theratechnologies' public filings. The reader is cautioned to consider these and other risks and uncertainties carefully and not to put undue reliance on forward-looking statements. Forward-Looking Statements reflect current expectations regarding future events and speak only as of the date of this press release and represent the Company's expectations as of that date.

The Company undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise, except as may be required by applicable law.

Contacts:

Media inquiries:

Julie Schneiderman
Senior Director, Communications & Corporate Affairs
communications@theratech.com
1-514-336-7800

Investor Inquiries:

Joanne Choi
Senior Director, Investor Relations
jchoi@theratech.com
1-551-261-0401